IMPROVING RECALLS
AT THE FOOD SAFETY AND INSPECTION SERVICE

Report of the Recall Policy Working Group

Food Safety and Inspection Service
United States Department of Agriculture

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THE RECALL PROCESS

FSIS alerted to potential recall

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Emergency Response Division evaluates preliminary information and informs plant

↓

Recall Committee meeting
(1) assess hazard (classification)
(2) identify product subject to recall
(3) identify production and distribution
(4) determine depth of recall

↓

Recall Committee contacts plant
(1) Informs it of recommendation
(2) Additional information is gathered by the Recall Committee

↓

Plant decides whether it will recall

↓

If not, FSIS decides whether to detain and seize product

If so, plant contacts consignees to return product

↓

Press release or other appropriate publicity issued

↓

Compliance visits plant to verify distribution records
(1) Traceback occurs, if necessary
(2) Compliance also conducts effectiveness checks

↓

Compliance recommends recall be terminated

↓

ERD terminates (closes) recall

INTRODUCTION AND EXECUTIVE SUMMARY

Background

The Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA) is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), which require Federal inspection and regulation of meat, poultry, and egg products prepared for distribution in commerce for use as human food. When meat, poultry, or egg products in commerce are found to present an actual or potential health hazard to consumers, or otherwise violate the provisions of the Acts, FSIS will request that firms recall the suspect products.

The purpose of a recall is to effect the removal from commerce of meat, poultry, or egg products that there is reason to believe are adulterated or misbranded. Even though the product has been inspected and passed, information has become available that provides reason for FSIS to believe that the product is, in fact, no longer eligible to bear the mark of inspection.

Recall actions are initiated by a firm, either on its own initiative or at the request of FSIS. If a firm does not agree to initiate a recall, FSIS has authority to detain and seize the product once it is located. A recall may be undertaken by any firm (i.e., business entity) that manufactures, wholesales, distributes, or retails meat, poultry, or egg products. A firm can be a manufacturer, wholesaler, distributor, or retailer. Firms can be large corporations, partnerships, or family owned businesses.

When a situation arises in which it may be necessary to request a recall, FSIS convenes a committee (the Recall Committee). The committee will request a recall if it determines that there is reason to find that the product is adulterated or misbranded. It also assigns a priority to the recall. A Class I recall involves a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Class II

recalls involve a potential health hazard situation where there is a remote probability of adverse health consequences from the use of the product. Class III recalls involve a situation where the use of the product is not likely to cause adverse health consequences.

During the recall, FSIS provides appropriate public notification, monitors the recall as it progresses, verifies the effectiveness of the recall, and ensures that corrective and, in HACCP plants, preventive actions are taken, so that firms produce, sell, or distribute products meeting all food safety and other regulatory requirements. A recall is considered officially terminated when FSIS determines that all reasonable efforts have been made to remove the violative product.

A recall should not be confused with a market withdrawal or a stock recovery, because the latter actions do not involve product that is believed to be or that is adulterated or misbranded under the acts. A market withdrawal is the voluntary removal or correction by a firm of a distributed product that involves a minor infraction that would not warrant legal action by FSIS or that involves no violation of the acts. A stock recovery is the voluntary removal or correction by a firm of product that has not been distributed or that has not left the direct control of the firm, e.g., the product is located on premises owned by, or under the control of, the firm, and no portion has been released for sale or use. These actions are generally taken by a firm without any interaction with the government.

Agency actions

During 1997, industry initiated several major Class I recalls at FSIS' request, one of which involved over 25 million pounds of product believed to be contaminated with *E. coli* O157:H7. As a result of these recalls, many concerns were raised about the actions taken by FSIS and the recalling firms. For example, concerns were raised about the Agency's policy for handling recalls, the process for identifying affected product, industry's recordkeeping practices, and public and interagency notification procedures. As a result of these concerns, the Agency initiated a review of its recall policies and practices to determine whether changes are needed.

On September 24, 1997, FSIS held a public meeting on its recall policies and procedures. Approximately, 30 individuals made oral presentations at that meeting, and the Agency received a small number of written comments after the meeting.

In November 1997, FSIS created a Working Group to assess the adequacy of its current recall policies and practices, to consider the oral and written comments that the Agency had received, and to develop a set of recommendations on how recalls should be accomplished. The Working Group focused on three major topics: how FSIS administers recalls; how FSIS communicates with consumers, the industry, and other interested Federal and State agencies about recalls; and how FSIS should proceed after the recalled product is removed from commerce. Based on a full review of these and the other issues presented to it, the Working Group has determined that, while the Agency's recall policies and procedures are basically sound, improvements can be made to make them more consistent with the approach that the Agency is taking under the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) final rule and to enhance communication of information regarding recalls.

Thus, the recommendations in this report do not represent a call for radical departures in how FSIS administers recalls. They also make no effort to deal with the question of how FSIS would respond if Congress were to pass the pending legislation that gives the Agency authority to require a recall. Nor do they address how companies should react when they become aware of a situation that may require a recall.

What the Working Group has done is formulate a set of concrete and practical suggestions, within the context of the Agency's current statutory authority, that address the concerns raised within FSIS and USDA, in the public meeting, and in the written comments that the Agency received. The Working Group believes that if these recommendations are implemented, the Agency's recall process will be more efficient, its communication about recalls will be more effective and equitable, and the significance of the recall will be better assimilated by the Agency. The Working Group stands ready to help to effect its recommendations.

The Working Group recommends that:

1. The recalling establishment be responsible for effecting the recall, including identifying the product that is to be recalled, notifying consignees, and providing, when necessary to remove the product from commerce, public notification. FSIS' role should be to verify that the establishment is taking the necessary and appropriate actions to fulfill its role. (I.A., II.A.)[1]

2. FSIS request that each establishment identify a person for the Agency to contact about possible recalls (I.C.). Through this person, the Agency should provide the establishment with as much advance notice as possible that the FSIS Recall Committee will be meeting to consider whether to request a recall of product shipped by the establishment (I.B., C.). The Recall Committee should permit the establishment to make a presentation to it about whether a recall is warranted if the establishment wishes to do so and is able to do so in a timely manner (I.C.).

3. FSIS institute rulemaking to require that all entities that handle meat, poultry, or egg products include in their records, information that will enable them to trace all product from its entry into their facility to its shipment from the facility to specific consignees (II.B.). The Working Group also recommends that the Agency institute rulemaking to require that establishments have a written plan that defines how they will conduct a recall should the need arise (I.A.).

4.a. FSIS prepare and issue guidance materials on a firm's responsibility in a recall (I.A., C.). These materials should advise firms to contact the Emergency Response Division (ERD), Office of Public Health and Science (OPHS), or the District Manager of the district in which the establishment in question is located, to discuss a recall. They should also explain what the Agency will do if an establishment refuses to recall and explain what are acceptable dispositions of recalled product (I.C., III.B.). The Agency should include in the guidance materials a model letter that establishments can use to notify consignees and subconsignees of a recall (II.B.).

[1]The numbers in parentheses following each recommendation are the section or sections of the report in which the recommendation is discussed.

b. The Agency create a Standard Operating Procedure to capture its procedures for deciding whether to request a recall, and that it up-date the directive on recalls (8080.1) (I.B.). The Agency should also address in the directive how the Agency will respond to a finding by an outside laboratory of a pathogen in an inspected product (I.E.).

c. The Agency up-date the checklist that the Emergency Response Division faxes to establishments when it notifies them that the Recall Committee plans to meet, so that the checklist fully reflects the Agency's data needs (I.D.). ERD should also work with the Technical Service Center to develop more extensive work sheets to use in questioning a firm about a possible recall (I.C.).

5. The Agency expand the Recall Committee to include representatives of the Technical Service Center, the relevant District Offices, and the Food Safety Executive Management and Coordination Staff. A representative of the Centers for Disease Control and Prevention should be included on the committee for matters that involve a pathogen, as well as when an illness has been associated with a meat, poultry, or egg product (I.B.). Members should be given as much time as possible to prepare for a Recall Committee meeting (I.B.).

6. The Director of ERD, OPHS, be delegated authority to decide whether to request Class II and Class III recalls (I.B.).

7. The Agency expand the role of compliance officers (Compliance and Investigations Division, Office of Field Operations) in a recall to include actions before and during, as well as after, the Recall Committee's deliberations. Compliance officers should be dispatched to the establishment as soon as a possible need for a recall is identified (I.A., B.). Compliance officers should be available at the establishment to answer the Recall Committee's questions and to resolve issues while the Recall Committee deliberates (I.B.). They also should verify the records relied upon by the establishment (I.D.).

8. Except where the source of a problem is apparent at the recalling establishment, FSIS should regularly trace product back one level from the recalling entity, although a more extensive traceback, even to the producer of the animals that were the source of the product involved, may be appropriate in some circumstances (I.F.).

9. FSIS continue to defer, if possible, to State and local agencies in recalls involving retail-prepared product (I.G.).

10. A press release be issued if it will advance the purpose of the recall -- to remove product that there is reason to believe is adulterated or misbranded from commerce (II.A.). In all recalls, including those in which a press release is issued, the Agency should notify the public by making the Recall Notification Report available through constituent communications and on the Agency's website (II.A.).

11. FSIS also use the Recall Notification Report, which is prepared by the Media Communications Office, to provide early notification about a recall to State and local agencies, and to all FSIS Deputy Adminstrators and District Offices (II.C., D.).

12. FSIS maintain and improve its communications about recalls with the Food and Drug Administration, the Centers for Disease Control and Prevention, and other Federal agencies (II.C.).

13. District Offices be responsible for recalls of imported product by official import establishments that are located in their districts (II.D.).

14. After a recall, the establishment be responsible for determining the disposition of the recovered product, subject to FSIS verification (III.B.). FSIS must determine whether the fact that the establishment shipped adulterated product evidences a HACCP system failure that would justify enforcement action against the establishment (III.C.).

15. FSIS regularly assess whether a recall provides evidence of a need to change Agency policies, and whether the Agency's recall procedures worked effectively and efficiently in the recall (III.D.).

I. HOW FSIS DOES RECALLS

A. THE AGENCY'S ROLE IN A RECALL

ISSUE

How should FSIS approach a recall, and what should its role be once a firm decides to recall product?

DISCUSSION

Background

Class I and some Class II recalls involve products that can affect the public health. The longer these products remain in commerce, the greater the likelihood that they will cause illness or injury. Therefore, when a situation arises in which it may be necessary to request a recall, there is pressure on the Agency to move as quickly as possible to decide whether it will do so and to have in hand the information that it needs to perform its functions should there be a recall. Consequently, once the Agency learns of a problem that may result in a recall, it shifts into a crisis management mode.

The Working Group does not question in any way the need for a crisis management response to such situations. The Agency's job is to protect the public health, and if consumers are getting sick, or there is a danger that they could get sick, FSIS must move quickly. The Working Group points out, however, that the crisis management response should be informed by the paradigm shift that is underway in how FSIS carries out its regulatory responsibilities. The Working Group believes that if the Agency were to make a shift in its approach to recalls that parallels the shift that it is making in its approach to inspection under the HACCP final rule, recalls will still proceed quickly, but the Agency's efforts in the recall will be more focused, less rushed, and more consistent with the Agency's appropriate regulatory role.

The Agency's present approach to recalls was formed in an era in which FSIS' regulatory model was one of find and fix. If FSIS found a problem in an establishment, the Agency felt the responsibility to fix it, either directly, with inspectors actually doing the work, or indirectly, with

inspectors telling the establishment exactly what to do. One of the major changes effected by the switch to HACCP is a change in the accountability aspect of the regulatory model. Establishments now have an obligation to prevent problems and to ensure that they are adequately addressed should they occur. HACCP is designed to help the establishment satisfy that obligation. FSIS' role is one of verifying that the establishment is fulfilling its obligation and, if the establishment is not doing so, of acting to ensure that the establishment does.

Analogously, when there is reason to believe that adulterated product has left an establishment and entered commerce, FSIS has traditionally quickly shifted to the "fix" mode as soon as an establishment has decided that it will recall. Most significantly, this has meant to FSIS that it had to issue the most visible symbol of the recall - - the press release announcing it. For it to do so, FSIS has had to gather information about product distribution from the establishment even before the Recall Committee is convened because the Agency needs this information not only for verification purposes, but as stated above, because the Agency needs to make sure that the press release it issues (should one be necessary) accurately describes the scope of the recall.

Approach in a HACCP environment

It is the sense of the Working Group that the Agency's recall process would benefit if it were changed to reflect the Agency's emerging role under HACCP. Certainly, it will continue to be necessary for FSIS to move as quickly as possible to respond to emergent situations and to be able to decide whether to request a recall. However, the Agency's process is bound to benefit if its initial focus is limited to the question of whether a recall is warranted, and if it is not diverted by questions of how to effect the recall should the establishment agree to institute one. Moreover, in situations in which establishments decide to recall without being requested to do so by the Agency, there is no need for any exigent action by FSIS.

Once a firm decides that it will recall its product, the Agency's role should be one of verifying that the company's actions to effect it are appropriate. The establishment should be responsible for determining the scope of the recall and how best to notify its consignees and the public. The

Agency's activities should include verifying that the firm has identified the proper product, verifying that the firm is making the appropriate contacts through its distribution channels, and verifying the adequacy of the establishment's notification to consignees and the public.

The Working Group does not wish to overstate the significance of what it is suggesting. The Agency will still need to proceed with deliberate speed to gather the information that it will need to fulfill its verification role. For example, the Working Group believes that it makes sense, and is recommending, that compliance officers be dispatched to an establishment as soon as a problem that would justify a recall is identified (see "The Recall Committee," below). Nonetheless, the extra hours that the Agency would gain by being in a position of verifying that the recall is instituted in an appropriate manner, rather than feeling compelled to actually do many of the tasks involved in instituting the recall, will allow the Agency to proceed in a more measured and consistent way in response to reports that product that appears to be adulterated or misbranded has entered commerce. Better Agency decisionmaking should result.

The Working Group considered whether it would be a disincentive for firms to agree to recall a product if they had to accept primary responsibility for the conduct of the recall. The group agreed that it would not be. The general feeling of the Working Group was that the factors that would cause a firm to recall a product, either on its own initiative or at the request of the Agency, would outweigh any burden placed on the firm by acceptance of this responsibility. In fact, some firms may welcome the opportunity to determine the scope of the recall and the content of any press release.

This raises an important additional point about changes that are necessary in a HACCP environment. HACCP requires that establishments anticipate problems that are reasonably forseeable and define in their HACCP plans the steps that they will take should the problems occur. It is reasonably forseeable that, at some point, the type of problems that require a recall will occur at virtually every establishment. If an establishment waits until a situation that will require a recall occurs before deciding what it will do in a recall, it is almost guaranteed to make

an inadequate response, particularly if responsibility for defining and conducting the recall, in the first instance, is the establishment's. Therefore, the Working Group recommends that the Agency consider instituting rulemaking to require that, in conjunction with the shift of responsibility for recalls to the establishment and the implementation of HACCP, establishments develop and maintain a recall plan that, similar to the sanitation standard operating procedure and the HACCP plan, defines how the establishment will respond should a situation that requires a recall arise.

Transition

Finally, the Working Group agreed that it would be necessary to have some type of transition period if the Agency decides to expect firms to accept primary responsibility for how recalls are conducted. For example, for some interim period, at the time that an Agency representative advises a firm of the possibility that the Agency may request a recall, he or she could offer the firm an option as to how the recall would proceed, either in accordance with traditional practice or with the firm taking full responsibility. After the transition period ends, the Agency would always assume a verification role. The Agency could issue guidance materials (see discussion on "Communication with Establishment About Whether It Will Recall," below) to explain a firm's responsibility in a recall.

RECOMMENDATIONS

The Working Group recommends that:

When establishments operating under HACCP initiate a recall, FSIS' role should be to verify that the establishment has appropriately identified the implicated product and taken all necessary steps to notify the recipients of this product, including if appropriate, the public, of the recall, and to take direct action only if the firm's actions prove to be inadequate;

FSIS institute rulemaking to require that establishments have a written plan that defines how they will conduct a recall should the need arise; and

When establishments not operating under HACCP initiate a recall, FSIS should coordinate the recall in the traditional manner. This option would no longer be available after the HACCP regulation is effective for all plants in January of 2000.

B. THE RECALL COMMITTEE

ISSUE

Should the roles, make-up, and operating procedures of the Recall Committee be formalized?

DISCUSSION

Roles and make-up

The Recall Committee traditionally has been responsible for analyzing the issues raised by an incident in which there may be product adulteration or misbranding; determining the degree of consumer risk involved and whether a recall is necessary; and making a recommendation to the Deputy Administrator, Office of Public Health and Science (OPHS), or to the Administrator, as to whether to request a recall. Over the years, the Recall Committee has come to have a consistent membership of organizational units that play set roles, even though neither the membership nor their roles are spelled out in any written form. The current roles of the organizational units that regularly participate in Recall Committee meetings are:

Emergency Response Division (ERD), OPHS: ERD is responsible for (1) gathering information on the incident and the establishment before the Recall Committee meets; (2) setting up and conducting the Recall Committee meeting; (3) ensuring that all of the appropriate parties are included in the meeting; (4) summarizing the meeting in the form of a memo with a recommendation to the Deputy Administrator, OPHS (in cases where there is no recall, notes are prepared for the file); and (5) maintaining a recall file.

Microbiology and Chemistry Divisions, OPHS: Microbiology and Chemistry are responsible for providing assistance in determining hazards and in interpreting laboratory analyses that either FSIS, the establishment, or a State or local agency has provided.

Compliance and Investigations Division (CID), Office of Field Operations (OFO): CID is responsible for conducting inquiries relevant to the recall; conducting effectiveness reviews to verify removal from commerce of adulterated or misbranded product by reviewing data on product codes and production level; and verifying that adequate notice about the recall has been provided to all consignees.

Media Communications Office, Food Safety Education and Communication Staff (FSECS): The Media office is responsible for assisting in developing press releases. This office is represented at meetings so that its staff is informed of recall actions and is able to communicate about those actions to the press and to concerned consumers.

Center For Disease Control (CDC): CDC has participated when there are known illnesses associated with the contaminated product.

The Recall Committee has generally been effective in taking decisive action and in communicating with establishments. Thus, the Agency units that have participated in the Recall Committee should continue to do so, and, with two exceptions, no changes in the roles that they play are necessary. The two exceptions are: First, the Working Group believes that the efforts of the Recall Committee will be facilitated if CID verified all information that an establishment provides to the Agency and not just the information that is used for conducting effectiveness reviews. The Working Group recommends that a compliance officer be dispatched to the establishment as soon as there is recognition of the possibility of a recall. The compliance officer will thus be available on site to answer the committee's questions and to assist in resolving issues. The compliance officer and the Inspector-in-Charge (IIC) at the establishment should work as a team in acquiring information.

Second, CDC should be included on the committee in all situations that appear to involve human pathogens, even if there have not been any known human illnesses associated with the product. Illnesses could occur later, and CDC's expertise is necessary in these situations.

Moreover, the Working Group is aware that, in some instances, the Recall Committee has lacked sufficient information on establishments and their operating procedures and on related industry practices. To remedy this problem, the Working Group recommends including the local District Office and the Technical Service Center on the Recall Committee. The District Office has specific knowledge of the establishment, and it can provide a local perspective. The Technical Service Center has knowledge of relevant industry practices. Both of these Agency units have recently

participated in Recall Committee meetings to great advantage. Therefore, the Working Group recommends that they be included as standing members of the Recall Committee.

Another problem for the Recall Committee has been the lack of consistency in who attends the committee meetings from the constituent organizational units. This lack of consistency has meant that time is wasted in familiarizing attendees with how the committee works and even on the status of a pending possible recall. To address this concern, the Working Group suggests that each organizational unit designate a person to serve on the Recall Committee as part of the responsibilities of his/her job, and that one alternate be designated. This change will greatly facilitate the works of the Recall Committee.

Finally, the Working Group notes that, recently, a Food Safety Executive Management and Coordination Staff (FSEMCS) member has been assigned to the committee to prepare any decision memoranda for the DA, OPHS, or the Administrator. This work has proven to be very useful, and the Working Group recommends that a representative of FSEMCS be made a regular member of the Recall Committee.

Operating procedures

The current operating procedures of the Recall Committee, as set out in the recall protocol, are as follows: (1) ERD alerts the Deputy Administrator of OPHS. (2) ERD alerts the establishment to the potential for a recall as early as possible and faxes a checklist containing needed information to the establishment. ERD allows 2-3 hours (minimum) for the establishment to obtain this information. The decision to recall product is time sensitive. As stated above, each day product is left in commerce, more illnesses can occur. For this reason, when ERD is alerted to a potential contamination problem, the Recall Committee is convened as quickly as possible. (3) The Recall Committee discusses the issues and decides what information is needed. (4) The committee calls the establishment to obtain the information that it needs. (5) The committee develops a recommendation and contacts the DA, OPHS, for concurrence. (6) The Recall Committee notifies the establishment of the Agency's request that it recall. (7) The committee prepares the

appropriate letters/memos.

Although the ERD's operating procedures have generally been effective, the Working Group believes that some improvements can be made in the process. First, although there is usually little time to prepare for a Recall Committee meeting, ERD should ensure that committee members are provided with any information the establishment has submitted as well as other relevant information on the incident and the establishment before the meeting to give the members a chance to review the issues and to come to the meeting prepared to discuss them. Second, to minimize the need to call the establishment as the Recall Committee deliberates, as stated above, when possible a compliance officer should be at the establishment to answer, with the IIC, the committee's questions regarding information provided by the establishment on the particular incident. Third, because a recall needs to proceed as quickly as possible, the committee frequently feels compelled to inform the establishment of the committee's recommendation that the establishment recall the product before it can obtain concurrence from the Deputy Administrator, OPHS, or the Administrator. Proceeding in this way sometimes undercuts the impact of the recommendation because the recommendation appears to be something less than the final Agency position.

The Working Group believes that this problem needs to be addressed. For Class II and Class III recalls, the problem can be remedied by delegating authority to decide whether to request a recall to the Director of ERD, subject, of course, to review by the Deputy Administrator or Administrator. For Class I recalls, the Working Group recognizes that the Deputy Administrator or the Administrator must play a role in making the decision whether to request a recall. However, the Working Group suggests that OPHS develop a procedure under which the Deputy Administrator will be available whenever the Recall Committee is ready to make a recommendation.

Reorganizing Recall Committee

One suggestion that was presented to the Working Group was that the Recall Committee be

divided into two groups: One group would continue to work on the issue of whether the Agency should request a recall and make any necessary follow-up contacts with the plant. For example, this group would coordinate the disposition of product if the approach that the establishment intends to take presents issues that are not covered by existing policy.

The second group would be a hazard evaluation committee, modeled in part after the Health Hazard Evaluation Boards used by the Food and Drug Administration (FDA). This group would rank the hazard and consider the public health aspects of the recall. Such a group could prove to be particularly useful in recalls involving pathogens.

The Working Group is not making a recommendation on this suggestion because it came to the Group's attention too late for the Working Group to give it full consideration. While the suggestion has obvious merit, the Working Group is concerned that splitting the Recall Committee may introduce some inefficiencies into the recall process. The Working Group notes that speed and efficiency are at a premium in recalls. FSIS, for example, has been much more prompt than FDA in classifying recalls. If the Working Group's recommendation on when a press release is needed (see section II.A. of this report) is adopted, however, the importance of prompt classification of a recall will be greatly reduced.

RECOMMENDATIONS:

The Working Group recommends that the Agency:

Capture existing and new procedures that it follows in a recall in a written Standard Operating Procedure (SOP), and up-date the Recall Directive, to reflect current Agency policy, procedures, and organizations;

In the SOP: (a) Define the membership of the Recall Committee to include CDC, the Technical Service Center, the appropriate District Office, and FSEMCS as active members along with the traditional members; (b) provide that establishments should be given as much time as possible to collect information on the incident prior to the Recall Committee meeting; and (c) charge CID with verifying all information that an establishment provides to

the Agency relative to a recall; and

For Class II and Class III recalls, authorize the Director of ERD to decide whether to request that an establishment recall product without concurrence from a higher level.

C. COMMUNICATING WITH AN ESTABLISHMENT ABOUT WHETHER IT WILL RECALL

ISSUE

What improvements can be made in how the Agency communicates with establishments that may need to recall product?

DISCUSSION

The importance of communication with industry in situations in which a recall is a possibility cannot be overstated. Recalls are voluntary. Thus, it is very important for the establishment to have a clear understanding of the situation and to feel that it has had an opportunity to present relevant information to the Agency. This understanding and opportunity come with good communication. In addition, many recalls are a result of establishments contacting the Agency to inform FSIS of a problem. When establishments do contact the Agency, good communication obviously is essential.

Agency contact

If an establishment is contemplating a recall, there is no ready way for an establishment to determine who in the Agency it should contact. The existing Agency directive on recalls (8080.1) states that in cases involving establishment-initiated recalls, the establishment is requested to notify the Regional Director, FSIS, or other inspection personnel in the region where the establishment is located. This suggestion is not helpful to establishments because there are no longer FSIS regional offices. The firm might decide, however, to notify the FSIS inspection personnel at hand – the IIC in the establishment. While it is appropriate for the establishment to do so, communication between the IIC and the appropriate people in headquarters (the Emergency Response Division, OPHS) has sometimes been slow and cumbersome. For example, the Working Group learned of an establishment-initiated recall that took place in December of 1997 in which it took 3 weeks for the report of a recall from an IIC to reach the ERD.

Therefore, the Agency needs to clearly define and clearly state how an establishment should notify

the Agency of a problem that may require a recall. The Working Group also recommends that the Agency advise establishments to contact both the ERD and the District Manager in their district. The ERD is obviously central in any recall. The District Manager is in a position to ensure that the information is rapidly communicated both to headquarters and to the IIC.

The best way for the Agency to convey this guidance to establishments and to other interested parties is through Agency-created guidance materials. These materials can provide industry with information about what to do and what is likely to happen if an establishment decides, or FSIS asks an establishment, to recall product. This guidance could also be used to convey other important information to the establishment, such as what the establishment's responsibilities are in a recall, what the Agency will do if the establishment does not agree to recall, and what are acceptable dispositions of recalled product.

Industry contact

When the Agency becomes aware of a situation that may require a recall, ERD calls the establishment and asks to speak to the manager or quality assurance manager. This request is sometimes fruitful and sometimes not. The Agency is occasionally left talking to a person without responsibility and left without any way of identifying a person with responsibility.

Thus, the Agency should request that establishments identify as part of their plant profile a person to contact in case a situation arises in which it may be necessary to recall product, that they provide a phone number for that person, and that they keep this information current. (This information would also be included in the establishment's recall plan (see section I.A. of this report).) Doing so will convey to industry the fact that there needs to be someone identified and reachable who is responsible for recalls. Many establishments have already recognized this responsibility and established recall teams. Other establishments need to assume this responsibility.

FSIS should list the responsible individual, with the phone numbers at which he or she can be

reached on a 24-hour basis, in the Meat and Poultry Inspection Directory, which it issues annually.

Early notification

FSIS should establish a procedure to ensure that it notifies an establishment that it may ask to recall product as soon as the Agency gets notice of a problem that could justify a recall. This procedure should state that ERD will contact the firm even before the Recall Committee meets.

Early notification is important for two reasons. First, it gives an establishment as much time as possible to conduct any investigation that it considers necessary to put itself in a position to decide whether it will agree to recall the product in question if the Agency decides to ask it to do so. (See Data Needs for Recalls, above.) Establishments are more likely to cooperate if they feel they are being treated fairly by the Agency.

Second, the Agency may find when it contacts the establishment that the establishment is aware of the problem and has decided on its own to initiate corrective action. Thus, early notification will help the Agency maximize its efficiency.

Develop new worksheet

ERD has a worksheet that it uses when it contacts an establishment about a possible recall. This worksheet requests information about the product in question. Soliciting this information has proven to be helpful to the Agency as it has tried to decide whether to request a recall.

However use of a general form, like the one ERD employs, has its limitations. Its generality has meant that it has not helped ERD to be as searching in questioning firms about a problem as it might, and consequently, there is concern that ERD has not questioned establishments in a way that would help establishments recognize problems that go beyond the immediate situation presented.

To give ERD insight into the questions that need to be asked in a particular situation, the Working Group recommends that ERD work with the Technical Service Center to develop worksheets that raise all relevant issues for a range of specific products. Use of these worksheets will enable ERD to look beyond the identified problem to other issues that may be presented by the product in question. The use of the checklists embodied in these worksheets will ensure that as many relevant issues as possible are raised and addressed before the Agency decides whether to request a recall. The checklist will also help to ensure consistency and objectivity.

Process for determining whether request for recall is justified

The Recall Committee sometimes finds itself confronted with situations in which there has been a tentative or presumptive finding that would justify a recall, but there is no collaborative evidence. In such situations, the committee's job is to determine whether the tentative finding can be validated. The question that is raised by such situations is what role the establishment should be allowed to play in the Recall Committee's deliberations.

The Working Group suggests that, if at all possible, any establishment that wants to make a presentation to show that the tentative finding is not valid be allowed to do so, as long as the establishment makes it in a timely manner. The judgment as to whether there is time for the establishment's involvement must be made on a case-by-case basis by the Recall Committee. If there is time, however, allowing the firm to make a presentation has two significant advantages: First, it will help to ensure that there is a full airing of the issues. The establishment may present evidence that convinces the committee that a recall is not appropriate. On the other hand, if it is not able to present convincing evidence, the establishment may come to see that a recall is in fact appropriate, even without collaborative evidence.

Second, as stated above, a recall is voluntary. If an establishment is asking to make a presentation instead of rejecting the notion of a recall outright, there is a good chance that, given the opportunity to be heard, the establishment will recall the product if asked to do so. The delay in reaching a decision that is necessary to allow the establishment to participate will be more than compensated for if the establishment recalls the product. The Agency will be saved the effort and

expense of having to find the product in commerce and of taking regulatory action against it (detention or seizure). Therefore, the Working Group recommends that Agency procedures include an opportunity for establishment participation if at all possible.

RECOMMENDATIONS

The Working Group recommends that the Agency:

Clarify and convey through guidance material that establishments should contact both the ERD and the District Manager in their district if they are comtemplating a recall;

Request that establishments identify as part of their plant profile a person to contact in the case of a recall;

Establish procedures for early notification of a company that a recall may be requested;

Develop documents that facilitate contacts with establishments; and

Allow establishments that want to do so, to make presentations to the Recall Committee in a timely manner.

D. DATA NEEDS FOR RECALLS

ISSUE

What data does the Recall Committee need to decide whether to request a recall (product, days of production, etc)? How should establishments respond to the Agency's needs?

DISCUSSION

Data and information are necessary to answer the fundamental questions of whether it is necessary to request a recall, and, if so, what products should be recalled. The determination to convene the Recall Committee to consider whether to request a recall can be based on FSIS inspectional or laboratory findings, an establishment's finding of misbranding or adulteration, consumer complaints, or epidemiologic data. If the Agency decides to request a recall, the products to be recalled are determined by the establishment based on its records and other evidence. This information is verified by a compliance officer, but traditionally this verification has not occurred until after the initial decision to recall product has been made. There have been cases in which recalls were expanded as a result of the Agency's verification findings. It is FSIS policy to request a recall of an entire day's production when an adulteration incident occurs. An establishment's production records, however, can limit the product to be recalled. A discussion of the records that are central to these determinations follows.

Information that suggests a need for a recall - - Assessing risk

Listed below in priority order are the types of information that the Agency may consider in deciding whether to request a recall:

1. Establishment records. Establishment records can facilitate efforts to pinpoint the product that was affected by a process failure and that should be recalled. They also can be used by establishments as evidence that suspect product is wholesome and not adulterated, and thus to limit the scope of a recall or to call into question whether there is, in fact, a need for a recall. As a result of the sanitation standard operating procedures and HACCP and their recordkeeping

requirements, there should be more industry records available for use for both of these purposes.

2. Consumer complaints. FSIS investigation of consumer complaints can lead to a finding that they involve an isolated incident or multiple occurrences. An isolated complaint has not usually resulted in an immediate recall. Repeated complaints about the same product have, however, resulted in recalls.

3. Evidence of adulteration or misbranding. Because the purpose of recalls is to remove from commerce product that there is reason to believe is adulterated or misbranded, an FSIS request for a recall is based on evidence that a problem exists. This evidence may come from the findings of FSIS inspectors and compliance officers or from FSIS laboratory results, which are developed using intact samples collected in an appropriate manner and analyzed using well-recognized methodologies. Reports from outside laboratories generally do not provide such support because the information necessary to establish the validity of sample collection, transportation, and laboratory analytical technique is not available. Usually, they will result only in FSIS targeting an establishment for additional sampling, although an establishment may decide on its own to recall product based on such reports.

4. Epidemiology data. State health departments' epidemiology investigations of reported illnesses associated with meat, poultry, or egg products have been the basis for recalls. Information on these investigations should include attack rates and odds ratios.

Data needs for defining scope of recall - - Identifying the product to be recalled

The scope of the recall refers to the products and days of production covered by the recall. In a typical recall, establishments have difficulty assembling the records that bear on the scope of the recall in a timely manner. If a compliance officer is on site, he or she can help the establishment to understand what records are relevant, as well as verify those records. The records that bear on the scope of the recall include:

1. Production Records and Product Codes. These records document how the product was formulated and produced, and whether any pathogen reduction interventions were included in the production process. Production records can include sample results, in-plant testing results, and in-plant inspection results. They should reveal the nature of any process control monitoring and of any verification actions employed by the establishment. Records on product codes provide a means to identify the product that is the subject of the recall. All product codes, testing results, and inspection findings should be related to dates, production shifts, or clean-up intervals to the extent possible.

2. Sanitation Standard Operating Procedures (SSOP). Records (establishment or FSIS) involving sanitation procedures, and documenting actions taken in response to any deficiencies, help to determine the scope of the problem if an SSOP failure occurs.

Both of these types of records can help to confine the scope of a recall to affected products. If an establishment does not maintain these types of records, it may be required to recall more product than might otherwise be the case.

Removing product from commerce

It is also necessary to decide what will be involved in removing the affected product from commerce. The records that are key to this inquiry are distribution records.

Distribution Records. Records on where and when the product was shipped are needed to determine the scope and the depth of the recall. Whenever possible, shipping records should be related to production periods by dates, shifts, or clean-up intervals. Having this information readily available will assist the Recall Committee in determining whether the recall needs to reach the consumer level, the retail level, or only the distribution level.

RECOMMENDATION

The Working Group recommends that the checklist that the ERD faxes to firms before the Recall

Committee meets be up-dated to reflect fully the Agency's data needs.

E. THE EFFECT OF PATHOGENS ON THE RECALL PROCESS

ISSUE

Should the fact that pathogens are deemed to be adulterants change the way that FSIS does recalls?

DISCUSSION

The basic issues involved in deciding whether to request a recall, and in identifying what product should be recalled, are not changed by the fact that pathogens are deemed to be adulterants. In deciding whether a situation that warrants a recall exists, the fundamental issues are the same regardless of whether the problem is caused by a pathogen, foreign material, some other adulterant, or a source of misbranding. The first inquiry is whether there has been a violation of the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. If there has been, attention quickly shifts to identification of the product involved.

Assessing risk

The fact that a pathogen is involved also does not affect the Agency's first basic inquiry and need -- to assess the risk involved. In making this judgment, the Recall Committee considers the probability and the magnitude of any harm that is likely to result from consuming the product. The intensity of the recall effort, as reflected in the classification that it receives, is related to the risk presented.

It is true that when a pathogen is involved, there is a reasonable possibility that use of the product will cause serious adverse health consequences. Thus, all recalls involving pathogens are Class I, and most Class I recalls in recent months have involved pathogens. However, Class I recalls are not the exclusive provence of pathogens. Foreign objects and animal drug residues are two types of adulterants whose presence in a meat or poultry product could require a Class I recall. Thus, the risk from pathogens does not require a change in how recalls are conducted.

Identifying product

As alluded to previously, identification of product that presents a risk is often difficult. Much of the controversy in the Hudson Foods recall, for example, arose out of the Agency's efforts to define the scope of the recall. In most cases in which it requests a recall, the Recall Committee tries to identify the product to be recalled by bracketing the production affected by the problem in question. Bracketing the product involves determining when and how the problem arose, and when, and if, it ended. What the Agency learns about how the problem occurred may lead it to trace the product back to the supplier in order to identify related product that is affected with the same problem (see "Tracebacks for Recalls" below), but this is true whether the problem was caused by a chemical, physical, microbiological, or other adulterant, or by a labeling error. Thus, the nature of the adulterant or of the misbranding does not change the Agency's second basic inquiry and need -- to identify the affected product.

Removing the product from commerce

The Agency's third basic inquiry and need in a recall is to identify those steps necessary to remove the affected product from commerce. This aspect of a recall sometimes involves tracing the product forward from the establishment to the retail level. While the risks associated with pathogens will affect the urgency of this effort, the fact that a pathogen is involved will not affect the basic nature of what it is that the Agency does in pursuit of this goal.

While the Agency's basic approach to recalls is not affected by the fact that pathogens are deemed to be adulterants, this fact does suggest one change that needs to be made in the Agency's policy statements on recalls. The Recall Directive (8080.1) is silent on how the Agency will react when a finding of a pathogen in an inspected product is made based on a sample that was not taken by FSIS. The Working Group considers this silence no longer to be appropriate.

The issues raised by such a finding are not simple. FSIS has traditionally responded to such a finding, in part because of a chain of custody concerns, by going back to the producer's establishment to get a sample of the product involved. This approach may not be adequately

protective of the public health, particularly when the Agency is able to test a sample of product from the same lot that the outside laboratory tested and is able to confirm the presence of the pathogen. Given this situation, the Working Group recommends that the Recall Directive be modified to set out a policy on how the Agency will react to reports of pathogens in inspected product that are not based on FSIS samples.

RECOMMENDATIONS

The Working Group recommends that:

The Agency not change its basic recall procedures when pathogens are involved. As Directive 8080.1 (the Recall Directive) states, recalls are actions to effect the removal of adulterated or misbranded product from trade or consumer channels. The fact that pathogens are adulterants does not require a change in this basic principle, nor does it require a change in the Agency's approach to recalls; and

The Recall Directive be revised to state how FSIS will react when the Agency receives a report of a finding of a pathogen by an outside laboratory, or some other source, in an inspected product.

F. TRACEBACKS FOR RECALLS

ISSUE

When should tracebacks be conducted? How far? For what purpose? Who is responsible for this activity?

DISCUSSION

Over the past few years, FSIS has made an effort to traceback the problems, particularly the presence of a pathogen, that have produced recalls to find where these problems may have originated. The Agency has justified doing so on the grounds that it needed to get a better understanding of the problems involved. Its actions have reflected the perceived consumer expectation that the Agency will find the source of problems with meat, poultry, and egg products. However, questions have been raised as to whether what FSIS has learned from these tracebacks has justified the resources that it has expended in doing them.

Limited approach to tracebacks

Two significant factors weigh heavily in support of a more limited approach to tracebacks. First, in a HACCP system, it is the establishment, not FSIS, that is charged with preventing problems from occurring. The establishment needs to have measures in place to ensure that source product entering the establishment is not adulterated. These measures should be adequate to protect the products that the establishment produces. If they are, then adulterated source product will be detected by the establishment and will not affect the establishment's products. If they are not, the establishment has a significant problem that requires FSIS' attention as well as the attention of the establishment. Thus, placing emphasis on tracebacks will divert FSIS' attention from where it belongs in a HACCP system.

The second factor that supports a limited approach to tracebacks is that the Agency simply does not have the resources to trace every problem that occurs back to its source.

Thus, FSIS' investigation when a recall occurs should focus on the establishment doing the recall. Nonetheless, the Working Group suggests that the Agency consider regularly tracing product that is the subject of a recall back one level to the establishment that produced the source product, unless, of course, it can be established that the adulteration or misbranding of the product occurred in the recalling establishment. If the establishment that produced the source product cannot be ruled out as the cause of the problem, traceback one level makes sense because it balances the need to find the source of the problem against the resource requirements of doing so. A one-level traceback will focus attention on whether that establishment has had a history of problems and will cause that establishment to review its processes. Such a traceback may also be useful in helping to determine whether the source of the hazard can be characterized as unforeseen (see 9 CFR 417). A one-level traceback, consequently, can help to ensure that the establishment does not produce adulterated or misbranded product.

A specific context in which traceback questions frequently arise is when adulterated product, particularly ground beef, is found at retail. If the retail store has used in-house trimmings in the ground beef, then a traceback does not make sense. However, if the establishment that was the source of the product, other than the in-house trimmings, used for grinding can be identified, it would make sense to inform that establishment of the problem. The establishment could factor this information into a review of its process. FSIS also would consider this information in deciding how frequently to sample product at that establishment.

If the product used to make the ground beef came directly from a federally-inspected establishment, FSIS would trace the product to the source establishment and conduct an appropriate investigation, including testing, at that establishment.

Given the importance of knowing exactly how product that is sampled at retail is made, that is, whether it contains in-house trimmings mixed with coarse ground, or whether it is directly from a Federal establishment, the Working Group recommends that compliance officers who take samples at retail be instructed to determine the ingredients, and their sources, used to make the

product on the sample form.

Exceptions to limited traceback

Although it recommends that product be routinely traced back one level, the Working Group is not suggesting that more extensive tracebacks should never be conducted. The Working Group believes that, if the facts in a particular case establish that a multi-level traceback would be useful or necessary to find the source of a problem, and thus to prevent the introduction of adulterated product into commerce, such a traceback would be justified. In appropriate cases, the Agency should even trace the animals that were used to make the recalled product back to the producer who supplied them. Even though the Agency would likely not have authority to take any legal action, what would be learned in the traceback could help to prevent recurrence of the problem.

The Working Group expects that the cases that would justify a multi-level traceback will be few in number. Nonetheless, when a multi-level traceback is necessary, the team formed to conduct it should include an epidemiologist as well as a compliance officer.

Finally, the Working Group stresses the need to ensure that when a traceback is conducted, the results of the traceback be captured in an accessible, regularized manner. The results must be captured in this way if the Agency is to benefit from the effort and resources expended in doing the recall.

RECOMMENDATIONS

The Working Group recommends that:

> Except where the source of the problem is apparent in the recalling establishment, FSIS should regularly trace product back one level from the recalling entity to the establishment (or establishments) that was the source of the product that is the subject of the recall. The purpose of this limited traceback is to determine whether the establishment that produced the source product has a problem, and thus, to determine whether a correction or other action is necessary at that establishment. Compliance should be charged with conducting

this limited traceback; and

In limited circumstances, to prevent the introduction of adulterated product into commerce, a more extensive traceback may be justified. In the limited circumstances in which such a traceback is done, use of an interdisciplinary team to conduct the traceback should be considered.

G. RETAIL RECALLS

ISSUE

What should FSIS' policy be for retail recalls involving retail produced product?

DISCUSSION

When FSIS finds evidence that a retail store has produced and sold adulterated product that presents a public health risk, the Agency's general approach is to contact both the store and the appropriate State health agency. FSIS' practice is to make recommendations concerning the need for a recall and offer assistance, but to allow State health officials to take the lead with respect to decisions concerning the need for a recall and press release. If FSIS has evidence of questionable production practices, it will refer these findings to State and local regulatory authorities. Similarly, if FSIS has evidence that a retail store has produced and sold adulterated or misbranded product that does not present a public health risk, the Agency will notify appropriate State and local regulatory authorities. Any need for a recall of product not posing a public health risk would be determined by State and local regulatory authorities.

Although the products produced in retail stores are exempt from Federal inspection, the adulteration and misbranding provisions of the FMIA and the PPIA apply to these products. Thus, FSIS has jurisdiction over products produced in exempt retail processing operations. Historically, FSIS has deferred to State and local regulatory authorities to enforce the adulteration and misbranding provisions of the statutes under comparable State laws/local ordinances. By "defer," the Agency means that State officials take the lead. The Agency does not relinquish its authority under the FMIA and PPIA. Situations that involve a potential recall should not be handled any differently.

To date, all FSIS retail recall experience has been related to the public health risks represented by findings of *Escherchia coli* O157:H7 in ground beef produced in retail stores. Following a confirmed positive sample from a retail store, FSIS contacts both the retail store and the

appropriate State health agency. FSIS offers recommendations and assistance but leaves the final decision to the State.

The ground beef testing program has raised issues of which State and local agency to notify, and of when to notify it. Currently, FSIS notifies an appropriate State agency (e.g., the State health department) at the same time the Agency notifies a retail store of a potential positive and notifies the State inspection programs when a potential positive could involve State inspected product. State health officials are notified when a sample is confirmed positive. There is no single point of contact at the State and local level.

The States have not responded consistently to findings of *E. coli* O157:H7 in retail ground beef. There have been five confirmed positives from retail ground beef since October 1994. In at least two cases, the retail stores and State health departments have issued a joint press release requesting that product be returned to the stores. Other cases have resulted only in a general public health alert reminding consumers to cook ground beef or in a decision that no action was warranted. If FSIS wants to ensure consistency or to ensure that a press release is issued, then FSIS needs to take control and respond to all confirmed retail positives. However, there is no reason to believe that FSIS control would have been more effective in removing potentially contaminated product from consumer channels than State and local control has been. While the decisions made by States have been different than what FSIS would likely have done, FSIS has not objected to any specific resolution. In other words, the States have provided an acceptable rationale for each of the retail recall decisions that they have made.

RECOMMENDATIONS

The Working Group recommends that, with respect to retail prepared products, the overall regulatory framework should continue to be that FSIS establishes public health standards and provides relevant information but defers to the States to take the lead in decisionmaking concerning recalls of retail prepared products. FSIS should accept State actions, unless the Agency is aware of specific facts that compel a different decision. In such a case, FSIS should

reserve the right to take appropriate action.

II. HOW FSIS COMMUNICATES ABOUT RECALLS

A. COMMUNICATION TO THE PUBLIC

ISSUE

When should there be public notification? What information should be included in the notification? Who should issue it, FSIS or the firm?

DISCUSSION

Current Policy on Issuing Press Releases

The Agency's current policy on issuing press releases is tied to the classification of the recall:

Class I Recalls

A press release is issued in Class I recalls of foods that are in packages that consumers can identify, can purchase, and may still have on hand in refrigerators, freezers, or cupboards.

A press release is not issued in Class I recalls where consumers do not see the package and, hence, cannot identify the product directly, such as product shipped to restaurants and large institutions.

Class II and Class III Recalls

A press release is issued in Class II recalls for unlabeled substances that can cause allergic reactions in some individuals or that some consumers want to avoid for religious or dietary reasons.

A press release is not issued in all other Class II recalls (i.e., those not involving unlabeled allergens or ingredients) or in Class III recalls because they do not involve significant public health risk.

This policy has led to confusion and controversy. Some have argued that press releases should only be issued when the product is in the hands of consumers. These people have argued that to issue a press release in any other circumstances would unfairly brand the product. On the other hand, many have argued that press releases should be issued in all Class I recalls, so that consumers are fully apprised of problems and are able to protect themselves. Another argument

for issuing press releases is to ensure that the public is fully informed of what the goverment is doing.

How, when, and by whom should press releases be issued?

The Working Group has carefully considered the arguments that have been presented on this question. It has concluded that the criteria for deciding what type of public notification is appropriate should flow from the purposes being advanced by the recall, not from the classification of the recall. The purpose of the recall is to remove from commerce product that there is reason to believe is adulterated or misbranded. Thus, the Working Group recommends that the Agency's policy be that a press release should be issued if it will help efforts to find affected product and remove it from commerce. If a press release would advance these ends, one should be issued regardless of how the recall is classified. If a press release would not advance that purpose, then one should not be issued.

As examples in the case of a recall of product that has reached consumers, it will be almost impossible to recover the product and remove it from commerce without a pres release. In the case of product that has reached subconsignees but not consumers, and the recalling establishment and its consignees have records that show exactly where the product has gone, the recall could probably be effected without a press release. On the other hand, if the product is in the hands of subconsignees, but neither the establishment nor its consignees have records that disclose exactly where the product is, a press release is likely to be necessary, even if there is reason to believe that none of the product has reached consumers. The press release would provide an important means of getting word of the recall to the people who had the product.

Some may argue that there is no reason to issue a press release if there is no public health concern e.g., in a Class III recall. The Working Group disagrees. A press release is justified in a Class III recall when it will advance the Agency's goal of getting unlawful product out of commerce. The press release can make clear that there is no health risk and thereby eliminate any basis for consumer concern about the product and forestall industry concerns about how the recall will

reflect on the product.[2]

Even when there is no need to issue a press release, the Working Group believes that the Agency's obligation to inform the public of the actions that it takes justifies appropriate public notification. All recalls should be the subject of a one page **Recall Notification Report** (sample attached), prepared by the Media Communications Office. When there is a Class I recall in which no press release is issued, the Recall Notification Report should be included as part of the FSIS Constituent Update or Alert. In addition, the **FSIS Constituent Report** should include a weekly listing of all recalls in the form of attaching the Recall Notification Reports. Finally, all Recall Notification Reports should be available at FSIS' website, and recalls will be summarized in the quarterly enforcement report.

Content of press release

The press release should include full information on: (a) product (including labeling) recalled; (b) problem with product, reason for recall, and how discovered; (c) name and location of the producing establishment and phone number of corporate spokesperson or point of contact; (d) numbers, amounts, and distribution; (e) classification, level of recall, and means of notification, i.e., how the establishment is getting the product back; (f) if recall is caused by presence of pathogen, a description of common symptoms of illness associated with that pathogen; and (g) FSIS follow-up activities and other agencies involved.

Product should be fully identified and as much information as possible given on where it is likely to be found. Information on what to do with the product, and on what to do if experiencing symptoms of foodborne illness associated with this product, should also be provided. Any safe handling procedures that consumers should follow also should be listed.

[2] Some have questioned whether product that is misbranded in a way that does not present a public health issue is an appropriate subject for a recall. Traditionally it has been. Class III recalls have involved product that is not likely to cause adverse health consequences. The Working Group is not aware of any basis for changing this longstanding policy.

The amount recalled is the amount in the affected lot less the amount that was never shipped or that is in warehouses in unopened packages that are under the exclusive control of the recalling company. A breakdown of *amount recalled* should include: the amount that has been returned and is under the control of the establishment, an estimate of the amount consumed, and the amount that remains in commerce.

Because the amount in commerce is subject to change, the press release should include a statement that reflects this uncertainty, for example, “It is believed that most of the product has been consumed.”

Timing

Multiple press releases can be confusing. However, sometimes significant new information becomes available after the initial release is published. For public health reasons, FSIS tries to issue a press release on the same day that the Recall Committee decides to request a recall. One solution is to publish a "Correction" or "Update" to the press release initially put out (referenced) with clarifying information. A second solution would be to revise and reissue the press release and at the same time remove the first release from circulation. The Recall Notification Report should also be updated, if necessary.

Who Issues?

FDA requires a press release for all Class I recalls of product that is in distribution. However, FDA rarely writes the press release. Most releases for FDA recalls are written by the company itself, which is also responsible for getting it out to the local press. About 15-20 FDA regional coordinators in the field provide model releases to the company and ensure that all necessary information is included in the press releases that are issued. Coordinators also verify that the releases get to the local press. The FDA press office keeps copies of all releases in case of inquiries. This alternate system in some ways reflects a HACCP-like paradigm, where the regulator requires the company to conduct a recall and notify its customers, while checking to

make sure that the company is doing what it needs to do to conduct the recall and notify the public. FDA only writes the release when a company refuses, which is rare.

One reason for the difference in FDA policy from that of FSIS is that FDA has a much larger number of recalls than FSIS and a small headquarters staff to write press releases. FDA does about 60-150 Class I recalls a year and does not have staff to write the releases. FSIS has about 20-25 Class I recalls per year.

FSIS should seriously consider adopting FDA's approach because it fits with the new paradigm that the Agency is implementing in conjunction with HACCP. (See "The Agency's Role in a Recall," above.) If FSIS adopted this system, it would be a major change, and it would require good planning if implementation is to occur without problems.

RECOMMENDATIONS

The Working Group recommends that:

All recalls be announced by some form of written notification, either a recall press release or a recall notification report. The recall press release should be used only when such a release will further the goal of removing adulterated or misbranded product from commerce. The Recall Notification Report (model attached) should be used for all recalls and should have as complete information as possible on the amount and distribution of the product, the location of establishment, and the identity of the parent company;

For public health reasons, when a press release is required, it should be issued the same day that the Recall Committee makes the decision to request a recall; and

The Agency consider moving in a HACCP-like direction, where firms would issue their own releases with FSIS in a verification role. Such a major shift should not be attempted without sufficient time for planning, putting in place a verification system, and redefining roles and responsibilities within and outside the Agency and for communicating with the interested and affected parties about the change.

RECALL NOTIFICATION REPORT

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

Product(s) Recalled: [brand name(s), product name(s), establishment number, type of package]

Production Dates/Codes: [sell-by date or other identifying codes]

Problem--Reason for Recall:

How and When Discovered:

Federal Establishment: [establishment number
company/establishment name
city, state]

Corporate Contact: [name of individual owner or firm that operates or manages the establishment, corporate level location, city, state; for media or other inquiries; include toll-free consumer inquiry number if they provide one.]

Quantity Recalled: [complete information on the amount and lots involved, production dates, distribution and location of the product, including a breakdown of what remained at the establishment, what left the establishment, what has been returned to the establishment, estimated amount that remains in commerce; account for all product recalled]

Distribution: [complete breakdown of retail and non-retail distribution, amounts sent to retail and to institution, fast food, etc.]

Recall Classification:

Recall Notification Level:

Press Release:

Direct Notification Means: [company notification letters, etc., sent to distributors, customers and consignees]

FSIS Follow-up Activities: [effectiveness checks, further follow-up testing, etc.]

Other Agencies Involved:

USDA Contacts:

Compliance/Recall Coordinator:	202-418-8872
Emergency Response:	202-501-7521
Media Inquiries:	202-720-9113
Congressional Inquiries:	202-720-3897
Consumer Inquiries:	1-800-535-4555
Web Site:	http://www.usda.gov/fsis

Date of Recall Meeting:

Recall Case Number:

B. COMMUNICATION PROBLEMS IN IMPLEMENTING RECALL

ISSUE

Are there changes that FSIS can make to facilitate improved industry communication during a recall?

DISCUSSION

Communication Between Recalling Entities and Their Consignees

A major problem in recalls is the communication between the recalling entity and its consignees and subconsignees. This communication frequently adds a significant amount of time to the recall and often is not very successful because consignees (distributors) do not have records that readily lend themselves to the type of traceforward that is necessary in a recall. For example, in the Beef America recall in October of 1997, there were great problems in identifying the subconsignees, and the Agency was forced, among other measures, to ask the Food Marketing Institute to contact its members to inform them of the recall.

To improve communication between recalling entities and their consignees and subconsignees, the Working Group makes two recommendations:

> The Agency should consider requiring that all entities that handle meat, poultry, or egg products include in their records information that will ensure that they will be able to trace all product, including ground beef, from its receipt into their facility to its shipment from the facility to specific consignees. To do so, the Agency will need to find under the Meat Inspection Act (MIA) that this information is necessary to fully disclose the transactions of those engaged in buying, selling, transporting, storing, or importing meat or meat products. The Agency will need to argue that full disclosure of the transactions of a firm involves not merely recording when it bought or sold product, but information that allows the firm to draw connections between its purchases and its sales. There are numerous reasons why the firm needs this information to fully document its transactions, including ensuring that its

inventory is appropriately flowing through its facility, that its pricing is appropriate, and that it can identify the supplier of a product if any defects in the product become apparent. Similarly, transporters and storers of meat need to be able to identify the product received, from whom they received it, and to whom they delivered it. Thus, there is an adequate factual basis for the Agency to find, at least tentatively in a proposal, that fully disclosing a transaction under the FMIA means making available the information that will provide the basis for making a connection between a firm's purchases and sales.

FSIS will also need to find this authority in the Poultry Products Inspection Act (PPIA). Actually, under the PPIA, the statutory basis for such a requirement is even clearer. Under this statute, the Secretary is authorized to require that firms keep "such records as are properly necessary for the effective enforcement of this chapter in order to insure against adulterated and misbranded poultry products for the American consumer." Records that provide the ability to trace product from receipt to shipment to specific consignees clearly advance these purposes. (See also section 4 of the Egg Products Inspection Act, which provides similar authority.)

The Working Group strongly recommends that the Agency institute rulemaking to ensure that all entities that buy, sell, transport, store, or import meat, meat products, poultry, or poultry products, including restaurants, hotels, and institutions, maintain their records in a way that will support a responsive recall system.

In addition, the Working Group recommends that, as part of the guidance materials that it is suggesting that the Agency create, FSIS should include a model letter that establishments can use to notify consignees, and that consignees can use to notify subconsignees of a recall. Provision of a model may help to ensure that appropriate information about the recall is provided by the recalling firm.

Communication Betwen the Compliance Officer and the Establishment

Compliance officers are dispatched to recalling establishments to review the establishment's

records to verify the information on production and distribution that the establishment is providing to the Agency. As evidenced by its recommendation that compliance officers be in the establishment as the recall committee meets, rather than later in the process, the Working Group considers the work of the compliance officer to be very important.

However, the Working Group also is aware that compliance officers play various roles, including developing criminal cases. The question that is thus presented, in the context of how the Agency communicates with industry, is what the compliance officer should say about the possibility of what he or she learns being used in a criminal action.

The Working Group believes that compliance officers ought to be straightforward in their approach to the establishment. They ought to tell the establishment, when they arrive to verify records in advance of a recall, that they are there to verify facts. They also ought to make clear, however, that if the establishment is not forthcoming or misrepresents the facts, the information that the compliance officer obtains can be used in a criminal or other action against the establishment. The Working Group suggests that the existing protocol for compliance officers be reviewed to ensure that it is fully consistent with these views.

RECOMMENDATIONS

The Working Group recommends that, to improve communication between recalling entities and their consignees and subconsignees, the Agency should:

Institute rulemaking to (a) require that all entities that handle meat, poultry, or egg products include in their records information that will ensure that they will be able to trace all product, including ground beef, from its receipt into their facility to its shipment from the facility to specific consignees; and (b) ensure that all entities that buy, sell, transport, store, or import meat, meat products, poultry, or poultry products, including restaurants, hotels, and institutions, maintain their records in a way that will support a responsive recall system; and

Create a model letter that establishments can use to notify consignees of a recall.

C. INTERAGENCY COMMUNICATION

ISSUE

Is there a need for early notification of State and local agencies about a recall? Should FSIS communicate with FDA, CDC, and other Federal agencies about recalls? What role should FSIS play in recalls involving products other than meat, poultry, or egg products, e.g., school lunch?

DISCUSSION

Notification of States

The Working Group believes that there are several important reasons why State and local governments should be notified as soon as possible after an establishment has decided to recall product. First, as representatives of State and local governments have pointed out, they receive inquiries from both the press and consumers about a recall when one is announced, even if they are not involved in the recall. To facilitate prompt and accurate communication about the recall, and to avoid confusion, it is important that these agencies be in a position to respond promptly and informatively to the inquiries that they receive.

The second important reason why State and local agencies should be given early notification is that they are likely to be in a position to spread word of the recall to retail stores, hotels, restaurants, and institutions. Notification to this level in the food distribution chain is important but sometimes difficult to effect.

Thirdly, with knowledge of the recall, State and local authorities can assist FSIS in determining whether there are any illnesses that are attributable to the product that is the subject of the recalls.

The Working Group note, that, despite these factors, FSIS has not always done a good job of keeping State and local agencies informed. However, the Agency is moving to correct this situation. ERD has begun to fax the Recall Notification Report to State departments of health and agriculture and to State epidemiologists as soon as a decision to recall has been made. The Working Group recommends that ERD continue to provide this early notification to State

agencies.

Communication with other Federal agencies

The Working Group finds that there are at least three important reasons why FSIS needs to communicate with other Federal agencies. First, such communication will allow FSIS to draw on other agencies to address any needs that arise during a recall that FSIS cannot meet or to supplement the expertise that exists in FSIS. Two examples illustrate this point.

One example is CDC's regular involvement in Recall Committee meetings that involve products that have caused illnesses. Although FSIS employs epidemiologists who are well-qualified to handle the scientific issues raised by illness reports, CDC brings broad expertise to the committee. This expertise supplements that resident in FSIS and helps to ensure that the Recall Committee's judgments are as well-informed as possible.

The other example is provided by canning. FSIS is not rich in experts on this matter. If a situation were to arise in which canned food was implicated in an illness, or questions were raised about the integrity of a firm's canning process, FSIS might find it necessary to draw on expertise from outside the Agency. In such a situation, communication with FDA would facilitate drawing on that agency's expertise on canning to fill FSIS' need.

Second, there are instances in which FSIS and another agency share interests in a matter, and communication will help both agencies to fulfill their roles. For example, the Defense Department's commissary system buys a large amount of meat, poultry, and egg products. When FSIS becomes aware of a meat, poultry, or egg product recall, it is important that it notify the commissary system for two reasons. First, from FSIS' point of view, by doing so it is providing notification to a major distributor of product and, thus, is taking an important step to effect the recall. Second, from the commissary system's standpoint, it is being advised that it is in control of adulterated or misbranded product, which it has no desire to convey to its customers. Similar examples could be cited of instances in which FSIS shares interests with FDA, CDC, and other agencies that can be advanced by close communication about recalls. FSIS is negotiating with

FDA, for example, on how FSIS could expedite its communication about recalls with State agencies through FDA's computer network system. FDA is creating this system because of its own need to communicate with the States. These negotiations may result in a revision of FSIS' MOU with FDA on recalls or in a new MOU.

Third, there are, on occasion, major recalls that involve numerous Federal agencies. For example, the discovery last summer of dioxin in ball clay resulted in recalls that involved FDA, FSIS, the Environmental Protection Agency (EPA), and CDC. Because such recalls are likely to be national in scope and involve a great deal of food, how the agencies function, both individually and together, will be closely scrutinized by both Congress and the public. If the agencies are to function well, good communication among them is essential.

In recognition of this fact, as part of the Food Safety Initiative, the Administration has created the Foodborne Outbreak Response Coordination Group (FORCG) to develop a national comprehensive and coordinated foodborne illness outbreak response system. FORCG will function as a policy and communication apparatus. The Administrator as well as the Under Secretary for Food Safety and representatives of the Department of Health and Human Services, EPA, and various State organizations will be members of FORCG. Because of the role invisioned for FORCG, it is important that FSIS be an active participant in this group.

For all these reasons, the Working Group recommends that FSIS commit the resources required to develop and maintain effective communication with other Federal agencies about recalls.

Products other than meat and poultry

FSIS can play an important role in recalls of products other than meat, poultry, and egg products. As FSIS builds its relationships with FDA, CDC, the States, and other agencies through improved regular communication and bodies like FORCG, it will be in a position to facilitate and coordinate recalls that involve other USDA agencies and non-USDA agencies. For example, there may be a recall of a non-FSIS inspected product in the school lunch program. FSIS would be able to put Food and Nutrition Services (FNS) officials in contact with officials at FDA and CDC who could

help them to understand the significance of the problem and how best to address it. The FSIS role would not be extensive or intensive, but it would help the recall to move as quickly and effectively as possible.

FSIS also needs to be informed of recalls that involve products other than meat, poultry, and egg products and to be involved in determining the effectiveness of these recalls in certain limited circumstances. There are FSIS-inspected products that include non-meat, -poultry, or -egg product ingredients. For example, stews and frozen dinners are likely to contain vegetables as well as meat or poultry. If there is a recall of the vegetables in these products, FSIS will need to request the recall of the products themselves.

Thus, FSIS needs to be advised by FDA of recalls of products that may have been shipped to meat, poultry, or egg product processing establishments. It also needs to develop close links with FNS. Communication of this type is usually facilitated if there is a regular point of contact in FSIS for other agencies. The Working Group believes that the best candidate as the focal point for such contacts is the Director of the ERD. This person is in a position to take action if it appears that a recall may be necessary and, through experience and training, would be an extremely valuable resource to FNS or any other agency that contacts him/her.

RECOMMENDATION

The Working Group recommends that the Agency:

Give early notification of a recall to State and local agencies; and

Make a significant effort to maintain and improve its communication about recalls with other Federal agencies.

D. INTRAAGENCY COMMUNICATION

ISSUE

What changes in the Agency's internal communications will improve the recall process?

DISCUSSION

The majority of the Agency's internal communications about recalls take place in the context of the Recall Committee. Thus, the Working Group has addressed most intraagency communication issues in its discussion of the make-up and operating procedures of the Recall Committee earlier in this report. There are, however, two other relevant matters.

1. The Working Group suggests that the ERD use the Recall Notification Report (see "Communication to the Public," above) to notify all FSIS Deputy Administrators, all components of the Office of the Administrator, and all FSIS District Offices of a recall. Use of the report in this way will ensure that there is prompt notice of recalls within the Agency.

2. Recalls of products that were imported are sometimes difficult to effect. The Agency's field import staff has traditionally been responsible for providing information on such product, but as a result of the shifts in authority that have occurred as a result of the reorganization of the Office of Field Operations, the Working Group believes that it would make sense if procedures were changed to have the Recall Committee communicate with the relevant District Office on recalls of imported products. The District Office should be responsible for ascertaining the necessary facts about the product at issue, including whether the importer is holding it or has shipped it. The District Office should be responsible for communicating that information to the Recall Committee, which, with the information in hand, would take steps to effect the recall. This communication will be facilitated if the Working Group's recommendation to include the District Office on the Recall Committee is adopted. The District Office should also advise the Assistant Deputy Administrator for Domestic and International Policy, OPPDE, and the Technical Service Center of the recall. The former must be able to respond to any inquiries about the recall from foreign governments, and the latter needs to be aware of the information in doing its reviews of the food

safety program in the country that was the source of the product.

RECOMMENDATIONS

The Working Group recommends the following changes to improve intraagency communication:

That the recall notification summary be used by ERD to notify all FSIS Deputy Administrators, all components of the Office of the Administrator, and all FSIS District Offices, of recalls; and

That the District Office be responsible for communicating with the Recall Committee on imported product that is involved in recalls.

III. AFTERMATH OF RECALLS

A. RECOVERY OF RECALLED PRODUCT

ISSUE

What actions can FSIS take to maximize the amount of product recovered in a recall?

DISCUSSION

Problems in recovering product

A recent report by a non-profit group raised questions about the adequacy of FSIS' recall procedures based on the small amounts of product that are usually recovered in recalls. The report pointed out that frequently less than half of the product recalled is recovered.

Because of the concerns raised in this report, the Working Group examined the issue of whether there are modifications that can be made to the Agency's recall procedures that will result in larger product recoveries.

The Working Group has identified four factors that affect the amount of product recovered in a recall.

1. Time before discovery of the problem - Recovery of product from commerce is dependent on when the problem with the product is found. The more time between the product's entry into commerce and the discovery of the problem, the less likely it is that the product will be recovered. Thus, if an establishment recalls a product soon after shipment, recovery is fairly straightforward and likely to be sucessful. If days or weeks pass before the problem is discovered, the problems in recovering product increase greatly, as product is distributed and consumed.

Time is often a factor in identifying problems because not all of the surveillance techniques used with meat and poultry lend themselves to providing immediate results. Testing product for pathogens, for example, usually requires 3-7 days before the results are available. The product is likely to be shipped by most establishments at the beginning of this 3-7 day period.

2. Shelf life - The shelf life of the product will affect how much of it will be recovered by a facility. Fresh meat and poultry products have a low likelihood of recovery because they have very short shelf lives. Most establishments will ship fresh product to distributors on the day that they produce it, and distributors quickly pass it on to hotels, institutions, retail stores, and restaurants. The product is generally consumed within 3-7 days of production. Thus, in a recent recall of fresh ground beef, over 400,000 pounds of product were recalled, but only 400 pounds were recovered.

Frozen or shelf stable product has a higher probability of being recovered. There is much less urgency to move these products through the system and to consume them. Thus, if these types of products are recalled, there is a good possibility that they will still be with the distributor or retailer, or on the consumer's shelf, and thus recoverable.

3. Identification of consignees and subconsignees - In at least one recent recall, product identification was hampered because there was no way to trace the implicated product through the distribution system. Although the establishment could identify the consignees of the product, most of the consignees could not determine what had happened to the product after they received it. This situation greatly complicated recovery efforts.

4. Communication difficulties - The Agency has found that many establishments do not have a set of model letters or other planned method for notifying consignees if it becomes necessary for them to institute a recall. These establishments try to decide how they will notify their consignees after they decide that they will, in fact, recall their product. As a result, issuance of the notification is delayed, and, as explained above, delay limits product recovery.

Actions That the Agency Can Take

The Working Group has considered whether, in light of these problems, there are actions that the Agency can take to increase the amount of product recovered. Obviously, the Agency's recall procedures cannot speed up the discovery of problems with product (although compliance with the HACCP regulations should minimize the possibility that adulterated product will enter

commerce), and they cannot cause industry and consumers to handle fresh product as they would shelf-stable product (nor would FSIS want its procedures to have that effect). What the Agency can do is take steps that will ensure that if a problem with product is discovered, measures are in place that will facilitate identification and tracking of the implicated product and communication with the people that may be in possession of the product, be they distributors, retailers, or consumers, so that any impediments to product recovery are minimized.

The Working Group has outlined steps in other sections of this report that it believes will be helpful in accomplishing these goals. A recall plan will greatly facilitate an establishment's reaction to a problem that requires recall (see "The Agency's Role in a Recall;" above). If all entities that handle meat and poultry are required to include in their records information that will ensure that they are able to trace the product that they handle, it will greatly facilitate rapid identification and tracking of implicated product (see "Communication Problems in Implementing Recall," above). In addition, if a model letter exists that establishments can use to notify their consignees of a recall (see "Communication Problems in Implementing Recall," above), and if a press release is routinely issued when it will facilitate the removal of product from commerce (see "Communication to the Public," above), it will facilitate rapid communication of an establishment's decision to recall. While the problems listed above will continue to make product recovery difficult in many situations, implementation of these recommendations will help to create a responsive system that maximizes the amount of product that is recovered in a recall.

B. DISPOSITION OF RECALLED PRODUCT

ISSUE

What should be the disposition of the recalled product?

DISCUSSION

Traditionally, FSIS has viewed a recall to be complete when the product in question has been removed from commerce. It has not viewed the disposition of recalled product to be a part of the recall. However, the Working Group has considered this issue as part of its review of the Agency's recall policies and policies related to recalls.

The framework for dealing with the recalled product that is recovered from commerce has been provided by the regulations on returned product, including 9 CFR 318.2, 318.3, 325.10, and 318.181. These regulations have imposed a strict command and control regime. They require that FSIS be notified when recalled product is being returned to an establishment, and that FSIS be given an opportunity to reinspect the product before it is used in any production operations. The Working Group believes that these regulations should be reassessed by the Agency in light of its HACCP regulations.

What can be done with product

Under the HACCP regulations, which became effective on January 26, 1998, for large establishments, FSIS has determined that the industry is responsible for producing and marketing products that are safe, unadulterated, and properly labeled and packaged. Section 417.3 places responsibility on the establishment to ensure that "no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce." In this regard, establishments are expected to perform a review to determine whether all records that relate to production of the product are complete, and whether all critical limits have been met. If a problem is found, the establishment may reprocess the product in a manner that is designed to ensure that the product is not adulterated when distributed to the consumer. The nature of the reprocessing, if any, will depend on such factors as the product, the potential hazard, and the

standards for compliance. The proposed disposition and subsequent product preparation and handling requires verification by inspection program personnel.

Product that has been recalled is, by definition, product in which a problem has been found. Even though the product was inspected and passed, information has become available that provides reason for FSIS to believe that the product is, in fact, not eligible to bear the marks of inspection. Thus, upon its return to the establishment, the product must be reprocessed in a way that will ensure that it is not adulterated or misbranded, or, if this is not possible, disposed of in a way that will ensure that it will be not used for human food.

The presence of *E. coli* O157:H7 in ground beef does not represent a special case when it comes to reprocessing. While this pathogen would render this product adulterated, this product may be further processed (i.e., cooked) in a manner that will destroy the *E. coli*. Such product may be transported under control procedures (see 9 CFR 325.10) for such further processing provided that the conditions of transportation prevent distribution of the product to consumers until after such processing has produced *E. coli* O157:H7-free food. The Meat and Poultry Inspection Advisory Committee has recommended to the Secretary of Agriculture that the Department issue a clear statement that product that was found to contain *E. coli* O157:H7, but that has been subjected to processing that will destroy pathogenic organisms, is safe for human consumption.

Disposition of recalled product belonging to a distributor generally cannot be handled within distribution facilities. A distributor usually does not have the capability to reprocess product and must take action to find a federally-inspected establishment that is able to reprocess the product in a manner acceptable to FSIS.

With respect to imported product that has entered this country, once a shipment has been inspected and passed for entry into the United States, that product is considered the same as all other domestic product. The types of actions that may be taken with respect to it are generally the same as for product of domestic origin. Thus, all issues related to recall and disposition of imported product that has entered the U.S. would be handled in the same manner as they are for

domestic product. Some imported product is sampled at the port of entry and held pending the sampling results. This product is not considered to have entered U.S. commerce. If the sample results are positive, the product may be refused entry and returned to the exporting country. If they are negative, the product enters the U.S.

RECOMMENDATIONS

The disposition of recalled product should be determined by the establishment, subject to verification by FSIS. For establishments operating under the HACCP regulations, products that are recalled for food safety reasons and returned to the establishment for disposition will usually represent either a deviation from a critical limit or an unforeseen hazard. As such, FSIS expects that establishments will follow 9 CFR 417.3(a) or (b) in addressing the disposition of the products. FSIS is responsible for verifying that the regulatory requirements (e.g., 9 CFR 417.3) are met and for taking appropriate regulatory actions when they are not.

C. REVIEW OF PROCESS CONTROL SYSTEMS AT RECALLING ESTABLISHMENT

ISSUE

For establishments that are subject to HACCP, what action should the Agency take with respect to a process control system that was used to produce product that was the subject of a recall?

DISCUSSION

As explained previously, establishments recall product, either on their own initiative or at FSIS' request, because there is reason to believe that that product is adulterated or misbranded. Thus, a recall is very significant for an establishment operating under HACCP because a HACCP system is supposed to be designed to prevent the production and shipment of adulterated food. If adulterated product has been produced and allowed to leave the establishment and enter commerce, there is a basis for significant concern about the adequacy of the establishment's HACCP system.

A HACCP system may be found to be inadequate if:

- The HACCP plan in operation does not meet the requirements set forth in Part 417 (9 CFR 417.6 (a)),
- Establishment personnel are not performing tasks specified in the HACCP plan (9 CFR 417.6 (b)),
- The establishment fails to take corrective actions, as required by 9 CFR 417.3 (9 CFR 417.6(c)),
- HACCP records are not being maintained as required in 9 CFR 417.5 (9 CFR 417.6(d)), or
- Adulterated product is produced or shipped (9 CFR 417.6(e)).

The release of adulterated product into commerce, and the resultant recall of that product, provides at least prima facie evidence that the establishment's HACCP system is inadequate under 9 CFR 417.6(e), and that it has failed.

However, this prima facie evidence should only be the beginning of the Agency's inquiry rather than the end. Evidence of a HACCP system failure is very significant because it would likely provide the basis for FSIS to withhold the mark of inspection and to consider suspending inspection. Before taking such a significant action, the Agency should determine whether there was a system failure, or whether the adulteration resulted from an unforeseen hazard (9 CFR 417.3(b)). The Agency's finding on this issue will determine how it proceeds, and thus, the actions that the establishment must take for it to remain in operation.

Some type of corrective action will also likely be necessary following a recall in non-HACCP plants. To ensure that there is appropriate action, there needs to be communication within FSIS about the nature of the problem that caused the recall between ERD and the IIC and other people within the Office of Field Operations. A procedure that ensures that this communication occurs needs to be established.

RECOMMENDATIONS

The Working Group recommends that the Agency routinely determine whether recalls by establishments subject to HACCP evidence a system failure that would justify taking enforcement action against that establishment.

D. REVIEW OF POLICY AND REGULATORY SIGNIFICANCE OF RECALLS

ISSUE

Should the Agency conduct follow-up on every recall? Should the Agency regularly evaluate the recall process?

DISCUSSION

Recall Follow-up

Recalls of meat or poultry products have traditionally encompassed the immediate action to remove suspect product from commerce. In situations where illness or injury occurs, FSIS has attempted to determine what happened and why. However, the Agency has not done this type of follow-up after every recall, and, even when it has done so, the Agency has generally not made an effort to determine whether policy or other regulatory issues are raised by its findings.

This situation will change with the implementation of the HACCP regulations. As stated in the previous section, the Agency will now have to determine whether the product entered commerce as a result of a failure of the establishment's HACCP system or as a result of an unforeseen hazard.

Over and above the determination with respect to the particular establishment, there is a broader aspect of the significance of a recall to which FSIS needs to attend. The Agency should assess whether the problem that has led to the recall has industry-wide implications or is simply the result of a poor plan or poor execution of the plan by the establishment. If an industry-wide problem is presented, the Agency needs to evaluate whether a change in its regulatory approach is necessary.

This assessment should be conducted by field epidemiology officers from the districts, under the direction of the Emergency Response Division. It also needs to involve the IIC in the establishment, who would assess whether the findings of the assessment suggest the need for changes in that establishment. Each recall file and follow-up report should be reviewed by OPPDE to determine whether any Agency policy or procedure should be re-evaluated.

Evaluation of Recalls

Not only is there currently little effort to assess the policy significance of a recall, there is also little time spent assessing how successful the Agency's actions are in achieving the objectives that FSIS has set for recalls. While compliance officers regularly conduct effectiveness checks, there are no regular checks of whether the Agency's procedures are working effectively and efficiently to produce timely recall decisions and prompt communication of those decisions.

The Working Group recommends that, on a regular basis, for example, after every fourth or fifth recall or as otherwise needed, the Recall Committee and the Emergency Response Division consider what went well in the recall, and what went wrong.

The Working Group suggests that the Evaluation and Analysis Division, OPPDE, be called upon to provide a facilitator for these meetings. In-put both from people involved in doing the recall and from interested persons outside the Agency (e.g., State agencies) can be solicited as part of this evaluation process. Based on these meetings, ERD can decide whether any modifications of the Agency's recall procedures (e.g. SOP, directive) are necessary.

RECOMMENDATIONS

The Working Group recommends that:

FSIS conduct regular follow-up of recalls under the direction of ERD; and

ERD, in consultation with the Evaluation and Analysis Division of OPPDE, conduct regular evaluations of recalls to determine whether modifications of the Agency's recall procedures are necessary.

E. INDEMNIFICATION

ISSUE

Should FSIS indemnify firms that recall product in response to Agency requests that ultimately turn out to have been made in error?

DISCUSSION

Some comments that FSIS received as part of its review of its recall policies stated that there are situations in which the Agency requests that an establishment recall product based on epidemiological evidence that shows an apparent association between the product and illnesses, but that association is refuted by evidence that is subsequently developed. The comments stated that FSIS should indemnify the firms involved in such recalls. The Working Group strongly disagrees.

Recalls are voluntary. While the Working Group recognizes that a request from the government to take an action is likely to have some coercive effect, ultimately the judgment as to whether to recall the product is the firm's alone. The firm must accept responsibility for that decision.

While FSIS would have reason to believe that a recall would be in the public interest when it approaches a firm, it cannot compel the firm to recall the product. The firm decides how it will proceed based on the results of its questioning of the Agency, its review of its own records, its consultation with in-house and outside experts, any testing that it may do, and any other investigation that it may conduct. In reaching a decision, it weighs the possibility that it shipped adulterated or misbranded product and the consequences that would follow from that fact (e.g., consumer illness; damage to the product's or the company's name) against the costs of a recall and the possibility that evidence that vindicates its product exists or can be developed. The decision that the firm reaches is based on its judgment as to how these factors balance out, not the fact that FSIS has requested a recall.

The Working Group recognizes that firms are more likely to recall product if they know that they

will be indemnified if it turns out that it really was not necessary for them to have done so. Nonetheless, the Working Group recommends that the Agency's position be that, while it hopes that firms will cooperate with the Agency if FSIS requests a recall, the firm must make its own judgment, and that the Agency will not under any circumstances indemnify firms for conducting a recall.

RECOMMENDATIONS

The Working Group recommends that FSIS not indemnify firms that conduct a recall in any circumstances.